

(19)



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Office européen des brevets



(11)

EP 0 841 041 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
11.09.2002 Bulletin 2002/37

(51) Int Cl.7: **A61L 27/00, A61F 2/32,**
A61F 2/34

(21) Application number: **97309050.9**

(22) Date of filing: **11.11.1997**

(54) **Hip joint prosthesis**

Hüftgelenkprothese

Prothèse de l'articulation de la hanche

(84) Designated Contracting States:
DE FR GB IE IT

(30) Priority: **12.11.1996 GB 9623540**

(43) Date of publication of application:
13.05.1998 Bulletin 1998/20

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Description

[0001] This invention relates to artificial joints, such as hip joint prostheses, comprising two or more components with closely conforming articulating surfaces. More particularly, the invention relates to such artificial joints wherein the articulating surfaces are made of metal.

[0002] Artificial joints, such as hip joint, shoulder joints and knee joints, are extremely widely used in orthopaedic surgery. Hip joint prostheses are particularly common. Such prostheses comprise an acetabular component, often referred to as an acetabular cup, and a femoral component. The acetabular component is usually of generally hemispherical shape, and it provides a generally hemispherical inner articulation surface. The femoral component generally comprises a spherical or near-spherical head, attached to an elongate stem. In use, the elongate stem is located in the intramedullary canal of the femur, and the head is located within the acetabular component, to provide articulation between the femur and the acetabulum.

[0003] In the first hip joint prostheses, both the inner articulation surface of the acetabular component and the head portion of the femoral component were made of metal, such as cast cobalt chromium alloy. However, such metal-on-metal prostheses were largely superseded by the use of a modified form of acetabular cup, comprising a metal outer shell, and an ultra high molecular weight polyethylene insert. Although prostheses of the latter type have been used in very large numbers, there is some concern that articulation of a metal head in a polyethylene cup causes significant erosion of the cup, with polyethylene debris being released into the surrounding tissue. For this reason, attention is again being focused on metal-on-metal hip joint prostheses.

[0004] One currently available metal-on-metal prosthesis is the Metasul™ product distributed by Protek AG. The product literature for this prosthesis specifies that both the cup and the femoral component are made from a forged CoCrMo alloy called Protasul®-21WF. Protasul®-21WF is believed to have a typical carbon content of 0.2% by weight.

[0005] Surprisingly, we have found that improved wear is obtained if the two articulating surfaces of a metal-on-metal joint prosthesis are formed from metals which are mis-matched with respect to their carbon content. Accordingly, the present invention provides a joint prosthesis comprising a first component and a second component, the articulation surfaces of the first component and the second component both being formed from a cobalt chromium alloy, characterised in that the articulation surface of the first component or the second component is formed from a cobalt chromium alloy having less than 0.1% carbon by weight, and the other articulation surface is formed from a cobalt chromium alloy comprising at least 0.18% by weight.

[0006] Alloys having less than 0.1 wt% carbon are

hereafter referred to as low carbon content alloys. Preferably, low carbon content alloys used in the prostheses of the present invention contain no more than 0.07 wt% carbon, e.g. about 0.06 wt% carbon.

[0007] Alloys containing at least 0.18 wt% carbon are hereafter referred to as high carbon content alloys. Preferably, high carbon content alloys used in the prostheses of the present invention contain from 0.2 to 0.35 wt% carbon, e.g. about 0.22 wt% carbon.

[0008] The alloys which are used to form the prostheses of the present invention preferably comprise from 58 to 69 wt% cobalt, from 26 to 30 wt% chromium, from 5 to 7 wt% molybdenum and no more than 5 wt% of other elements. More preferably, such alloys comprise no more than 1 wt% nickel, 0.75 wt% iron, 1 wt% silicon, 1 wt% manganese and 0.25 wt% nitrogen. Although wrought alloys are preferred, cast or forged alloys may also be used. Wrought alloys having the composition set out above are described in ASTM F1537, while forged alloys of the same composition are described in ASTM F799. Cast alloys preferably have a chromium content of 27 to 30% by weight. A suitable cast alloy is ASTM F75.

[0009] Preferably, the joint prosthesis is a hip joint prosthesis wherein the first component is an acetabular cup and the second component is a femoral component.

[0010] The articulating surfaces of prostheses according to the invention will usually be substantially congruent. In the case of hip joint prostheses, such surfaces will be generally spherical, preferably with a departure from roundness no greater than 10 µm when measured in accordance with the minimum zone centre method given in ISO 4291. More preferably, the articulating surfaces will have a roundness error no greater than 8 µm, and most preferably no greater than 5 µm.

[0011] In order to minimise wear, the articulating surfaces of the prostheses of the invention will usually also be highly polished. Preferably, the articulating surfaces will have an R_a value (as measured in accordance with ISO 468) no greater than 0.1 µm, and more preferably no greater than 0.05 µm. Particularly preferred prostheses according to the invention will have articulating surfaces with an R_a value no greater than 0.02 µm.

[0012] Hip joint prostheses according to the present invention may take any of various forms. For example, the femoral component may be of the cemented or cementless type, and it may be provided with a collar for transmission of load to the calcar of the femur. Similarly, the acetabular component may be of the cemented or cementless type.

[0013] When cementless femoral or acetabular components are used in accordance with the present invention, they may be provided with porous outer surfaces to encourage attachment of bone, as is well known in the art. Suitable porous surfaces may be provided by a variety of procedures such as simple rough blasting, chemical etching or application of plasma sprayed layers. Sintered porous coating comprising beads, mesh

or fibre pads may also be used.

[0014] Cemented prostheses in accordance with the present invention will generally have relatively smooth surface finishes to prevent abrasion of the cement.

[0015] It will be understood that the prostheses of the present invention need not be made entirely from cobalt chrome alloy. For example, an acetabular cup may comprise a cobalt chrome alloy insert which provides the articulating surface, and an outer shell formed from titanium, titanium alloy, cobalt chrome alloy or even ceramic. Stainless steel could also be used for the outer shell if the insert and the shell are electrically insulated to prevent galvanic corrosion.

[0016] Similarly, a femoral prosthesis may comprise a cobalt chrome alloy head, and a stem formed from titanium, titanium alloy or cobalt chrome alloy.

[0017] An embodiment of a joint prosthesis in accordance with the present invention in the form of a hip joint prosthesis is now described with reference to the accompanying drawings, in which:

Figure 1 is a cross-sectional view of an acetabular component and a femoral head of the hip joint prosthesis;

Figure 2 is a perspective view of the outer shell of the acetabular component of Figure 1; and

Figure 3 is a perspective view of an insert of the acetabular component of Figure 1.

[0018] Figure 1 shows a hip prosthesis 1 comprising an acetabular component 12 and a femoral component 14. The acetabular component 12 is formed of an insert 18 with an inner articulating surface 20, the insert 18 being disposed within a shell 17. The insert 18 is of a wrought cobalt chrome alloy conforming to ASTM F1537 and having a carbon content of approximately 0.22% by weight, while the shell 17 is of a titanium alloy (Ti6Al4V).

[0019] The inner articulating surface 20 of the insert 18 is substantially congruent with the surface of a femoral head 16 of a femoral component 14. The femoral component 14 also comprises a femoral stem to which the femoral head 16 is attachable. Both the head 16 and the stem are of a cobalt chrome alloy conforming to ASTM F1537. However, in contrast to the insert 18, the alloy from which the head 16 is formed has a carbon content of approximately 0.06% by weight.

[0020] The insert 18 is generally hemispherical and has a portion of its outer surface 30 in the form of a band adjacent the rim 38 of the insert 18 which is angled to form a taper fit with an angled inner surface 32 of the shell 17. There is an area of clearance between the remainder of the outer surface of the insert 18 and the inner surface of the shell 17. The shell 18 has a groove 36 at its rim 38 in which an extraction instrument can be located.

[0021] The shell 17 of the acetabular component 12 has a ridged outer surface 22 which can be coated as discussed above to enhance the attachment of bone. The shell 17 of the described embodiment has three apertures 24 through which screws are placed for securement of the shell 17 to the patient's hip bone. The screws are attached prior to the insertion of the insert 18 into the shell 17. The apertures 24 are unthreaded and are dual tapered 34 outwardly towards the inner and outer surfaces of the shell 17. The smallest diameter 26 of each aperture 24 prevents the screw from passing through the aperture 24. The shell 17 also has an apical threaded aperture 28 for instrumentation attachment and for viewing.

Experimental

[0022] The wear of hip joint prosthesis components was assessed by subjecting an acetabular component and a femoral component to repeated articulation representative of a normal walking cycle. Testing was conducted using a model EW-12 hip simulator, manufactured by Materials Technology Inc., La Canada, California.

[0023] The femoral heads used in this evaluation had a diameter of 28 mm. The nominal clearance (cup diameter minus head diameter) between the femoral heads and the acetabular cups during testing was 0.050 mm. Actual clearances ranged from 0.045 mm to 0.054 mm. The components were subjected to a loading curve during testing that is equivalent to that developed during a walking cycle. Peak load was approximately 2000 N.

[0024] During testing the hip prostheses were completely immersed in bovine serum. Tests were conducted for up to two million cycles. Wear was assessed by measuring the total weight loss of the two components during testing.

[0025] In all cases, the prostheses had articulation surfaces formed from cobalt chromium alloy conforming to ASTM F1537. However, the samples differed in the carbon content of the alloy used. Low-carbon (approximately 0.06 wt% carbon) femoral components were matched with either low-carbon or high-carbon (approximately 0.22 wt%) acetabular cups, and high-carbon femoral components were similarly matched with either low-carbon or high-carbon cups. Surprisingly, the highest average wear (weight loss) was observed for prostheses in which the femoral head and the acetabular cup were both formed from low carbon content alloy, or both from high carbon content alloy. The lowest average wear (weight loss) was observed for prostheses in which a low carbon content alloy was used for the femoral head and a high carbon content alloy was used for the acetabular cup (or *vice versa*).

Claims

1. A joint prosthesis comprising a first component and a second component, the articulation surfaces of the first component and the second component both being formed from a cobalt chromium alloy, **characterised in that** the articulation surface of the first component or the second component is formed from a cobalt chromium alloy having less than 0.1% carbon by weight, and the other articulation surface is formed from a cobalt chromium alloy comprising at least 0.18% carbon by weight.
2. A prosthesis according to claim 1 wherein the articulation surface of the first component or the second component is formed from a cobalt chromium alloy comprising from 0 to 0.07% carbon by weight, and the other articulation surface is formed from a cobalt chromium alloy comprising 0.2 to 0.35% carbon by weight.
3. A prosthesis according to claim 1 or claim 2 wherein the first component and the second component are formed from an alloy comprising from 58 to 69% cobalt, from 26 to 30% chromium, from 5 to 7% molybdenum and no more than 5% (in total) of other elements, all percentages being by weight.
4. A prosthesis according to claim 3 wherein said alloy comprises no more than 1% nickel, 0.75% iron, 1% silicon, 1% manganese and 0.25% nitrogen.
5. A prosthesis according to claim 4 wherein said alloy is a wrought alloy.
6. A prosthesis according to claim 5 wherein said wrought alloy conforms to ASTM F1537.
7. A hip joint prosthesis according to any preceding claim.
8. A prosthesis according to claim 7 wherein the first component is a hip head prosthesis and the second component is an acetabular cup prosthesis.
9. A hip joint prosthesis, comprising
 - an acetabular cup having an articulation surface; and
 - a femoral head having an articulation surface,
 wherein the articulation surface of one of the acetabular cup and the femoral head is made of a metal alloy having a low carbon content and the articulation surface of the other of the acetabular cup and the femoral head is made of a metal alloy having a high carbon content.

10. A hip joint prosthesis according to claim 9 wherein the carbon content of the low carbon content metal alloy is in the range of 0.03 to 0.10 wt% carbon.
11. A hip joint prosthesis according to claim 9 wherein the carbon content of the high carbon content metal alloy is in the range of about 0.18 to 0.35 wt% carbon.

Patentansprüche

1. Gelenkprothese mit einem ersten Bestandteil und einem zweiten Bestandteil, bei welcher die Gelenkflächen des ersten Bestandteils und des zweiten Bestandteils jeweils aus einer Kobalt-Chrom-Legierung ausgebildet sind, **dadurch gekennzeichnet, daß** die Gelenkfläche des ersten Bestandteils oder des zweiten Bestandteils aus einer Kobalt-Chrom-Legierung ausgebildet ist, welche weniger als 0,1 Gewichtsprozent Kohlenstoff enthält und die andere Gelenkfläche aus einer Kobalt-Chrom-Legierung ausgebildet ist, welches mindestens 0,18 Gewichtsprozent Kohlenstoff enthält.
2. Prothese nach Anspruch 1, bei welcher die Gelenkfläche des ersten Bestandteils oder des zweiten Bestandteils aus einer Kobalt-Chrom-Legierung ausgebildet ist, welche 0 bis 0,07 Gewichtsprozent Kohlenstoff enthält und die andere Gelenkfläche aus einer Kobalt-Chrom-Legierung ausgebildet ist, welche 0,2 bis 0,35 Gewichtsprozent Kohlenstoff enthält.
3. Prothese nach Anspruch 1 oder 2, bei welcher der erste Bestandteil und der zweite Bestandteil aus einer Legierung ausgebildet sind, welche 58% bis 69% Kobalt, 26% bis 30% Chrom, 5% bis 7% Molybdän und nicht mehr als (insgesamt) 5% andere Elemente enthält, wobei alle Prozentangaben in Gewichtsprozent sind.
4. Prothese nach Anspruch 3, bei der die Legierung nicht mehr als 1% Nickel, 0,75% Eisen, 1% Silicium, 1% Mangan und 0,25% Stickstoff enthält.
5. Prothese nach Anspruch 4, bei der die Legierung eine Knetlegierung ist.
6. Prothese nach Anspruch 5, bei der die Knetlegierung ASTM F1537 entspricht.
7. Hüftgelenkprothese nach einem der vorangehenden Ansprüche.
8. Prothese nach Anspruch 7, bei welcher der erste Bestandteil eine Hüftgelenkkopfprothese und der zweite Bestandteil eine Hüftgelenkspfannenprothese

se ist.

9. Hüftgelenkprothese, welche umfaßt

- eine Hüftgelenkpfannenprothese mit einer Gelenkfläche und
- einen Femurkopf mit einer Gelenkfläche,

wobei die Gelenkfläche der Hüftgelenkpfannenprothese oder des Femurkopfes aus einem Metall mit einem geringen Kohlenstoffgehalt besteht und die Gelenkfläche des anderen Bestandteils (Hüftgelenkpfannenprothese, Femurkopf) aus einer Metalllegierung mit einem hohen Kohlenstoffgehalt besteht.

10. Hüftgelenkprothese nach Anspruch 9, bei welcher der Kohlenstoffgehalt der Legierung mit einem geringen Kohlenstoffgehalt in dem Bereich von 0,03 Gewichtsprozent bis 0,10 Gewichtsprozent Kohlenstoff liegt.

11. Hüftgelenkprothese nach Anspruch 9, bei welcher der Kohlenstoffgehalt der Metalllegierung mit hohem Kohlenstoffgehalt in dem Bereich von ungefähr 0,18 Gewichtsprozent bis 0,35 Gewichtsprozent liegt.

Revendications

1. Prothèse formant joint comprenant un premier composant et un second composant, les surfaces d'articulation du premier composant et du second composant étant toutes les deux fabriquées à partir d'un alliage de cobalt et de chrome, **caractérisée en ce que** la surface d'articulation du premier composant ou du second composant est fabriquée à partir d'un alliage de cobalt et de chrome ayant une teneur en carbone inférieure à 0,1 % en poids, et l'autre surface d'articulation est fabriquée à partir d'un alliage de cobalt et de chrome comprenant au moins 0,18 % en poids de carbone.

2. Prothèse selon la revendication 1, dans laquelle la surface d'articulation du premier composant ou du second composant est fabriquée à partir d'un alliage de cobalt et de chrome comprenant de 0 à 0,07 % en poids de carbone, et l'autre surface d'articulation est fabriquée à partir d'un alliage de cobalt et de chrome comprenant de 0,2 à 0,35 % en poids de carbone.

3. Prothèse selon la revendication 1 ou la revendication 2, dans laquelle le premier composant et le second composant sont fabriqués à partir d'un alliage comprenant de 58 à 69 % de cobalt, de 26 à 30 % de chrome, de 5 à 7 % de molybdène et pas plus

de 5 % (en tout) d'autres éléments, tous les pourcentages étant exprimés en poids.

4. Prothèse selon la revendication 3, dans laquelle le dit alliage ne comprend pas plus de 1 % de nickel, 0,75 % de fer, 1 % de silicium, 1 % de manganèse et 0,25 % d'azote.

5. Prothèse selon la revendication 4, dans laquelle le dit alliage est un alliage de corroyage.

6. Prothèse selon la revendication 5, dans laquelle le dit alliage de corroyage est conforme à la norme ASTM F1537.

7. Prothèse formant joint pour la hanche selon l'une quelconque des revendications précédentes.

8. Prothèse selon la revendication 7, dans laquelle le premier composant est une prothèse de tête fémorale et le second composant est une prothèse formant cupule acétabulaire.

9. Prothèse formant joint pour la hanche, comprenant :

une cupule acétabulaire ayant une surface d'articulation ; et
une tête fémorale ayant une surface d'articulation,

dans laquelle la surface d'articulation de l'un des composants parmi la cupule acétabulaire et la tête fémorale est fabriquée à partir d'un alliage métallique ayant une faible teneur en carbone et la surface d'articulation de l'autre composant parmi la cupule acétabulaire et la tête fémorale est fabriquée à partir d'un alliage métallique ayant une teneur en carbone élevée.

10. Prothèse formant joint pour la hanche selon la revendication 9, dans laquelle la teneur en carbone de l'alliage métallique à faible teneur en carbone se trouve dans la plage allant de 0,03 à 0,10 % en poids de carbone.

11. Prothèse formant joint pour la hanche selon la revendication 9, dans laquelle la teneur en carbone de l'alliage métallique à teneur élevée en carbone se trouve dans la plage allant de 0,18 à 0,35 % en poids de carbone.

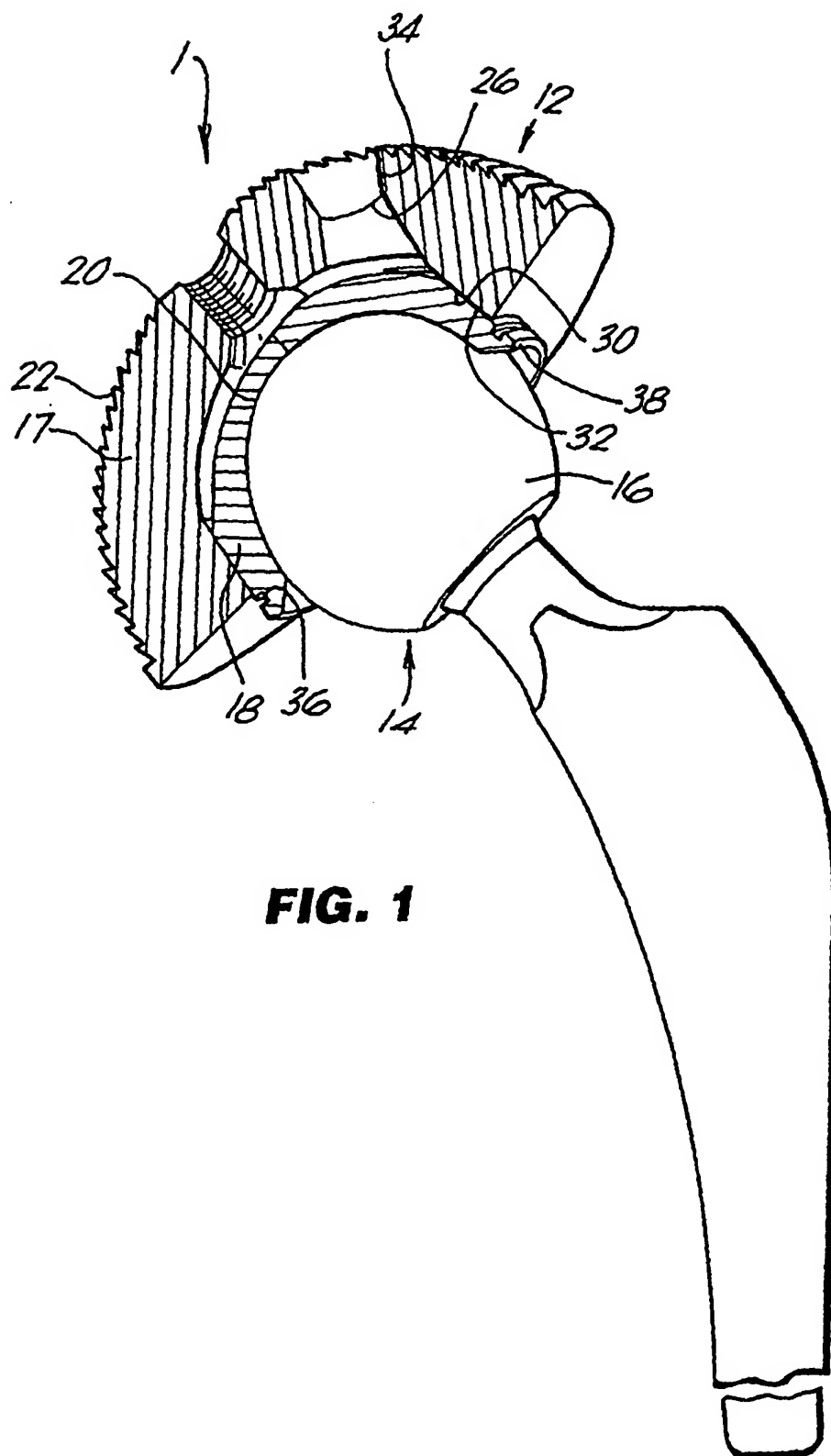


FIG. 1

FIG. 2

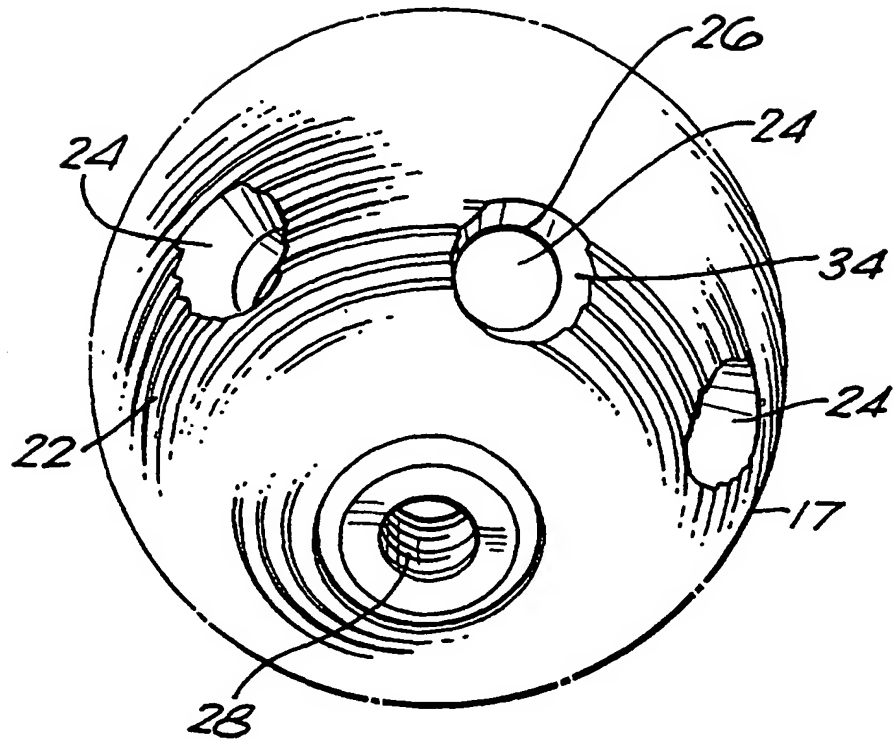


FIG. 3

